

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Addendum to provide additional information to subject after original consent

IRB Study #09-1625

Consent Form Version Date: January 12, 2011

Title of Study: Epigenetic effects of diesel exhaust and ozone exposure

Principal Investigator: David Diaz-Sanchez, Ph.D.

UNC-Chapel Hill Department: United States Environmental Protection Agency

UNC-Chapel Hill Phone number: 919-966-0676

Email Address: Diaz-Sanchez.David@epa.gov

Co-Investigators: Kelly Duncan, Ph.D. and Mike Schmitt, MSPH

Faculty Advisor: **Funding Source and/or Sponsor:** Government

Study Coordinator: Mike Schmitt, MSPH

Study Contact telephone number: 919-966-0647

Study Contact email: Schmitt.mike@epa.gov

The following information should be read as an addition to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent Form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your study doctor.

New or additional information

You are being asked to do one additional exposure. The conditions of the exposure and procedures pre- and post-exposure are the same as what are outlined in the original consent form. You will receive compensation for participating in one session:

Exposure Day 1 (6 hours)

venipuncture (~80ml, pre)	\$ 30 per exposure
Holter monitor	\$100 per exposure
chamber exposure (2 hours)	\$ 72 per exposure
venipuncture (~80 ml, post)	\$ 30 per exposure
spirometry (before and after exposure)	\$ 40 per exposure
time (4 h @\$12/h)	\$ 48 per exposure
Lunch:	\$ 5 per exposure

Day 1 total for completion of ONE exposure = \$ 325

Exposure Day 2 (4 hours)

Spirometry before bronchoscopy	\$ 20 per exposure
venipuncture (~80ml, 24h post)	\$ 30 per exposure
time (2h @\$12/h)	\$ 24 per exposure
Bronchoscopy	\$350 per exposure
Endobronchial Brush biopsies	\$25 per exposure

Day 2 total for completion of ONE exposure = \$449

Total for Completion of Additional Exposure = \$774

If you have any further questions, please call the Director of the NHEERL Human Research Protocol Office at 919-966-6217.

This addendum has been reviewed and approved by the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill. If you have any questions or concerns regarding your rights as a research subject, you may contact

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to continue to participate in this research study.

Signature of Research Subject

Date

Printed Name of Research Subject

Signature of Research Team Member Obtaining Consent

Date

Printed Name of Research Team Member Obtaining Consent